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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/601,655	08/04/2000	OSAMU SAKANAKA	20001081A	8304

7590 11/23/2001

WENDEROOTH LIND & PONACK  
2033 K STREET NW  
SUITE 800  
WASHINGTON, DC 20006

EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 11/23/2001

12

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/601,655

Applicant(s)

SAKANAKA ET AL.

Examiner

Binta M. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7,9,10,12-15 and 19-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,12-15 and 25 is/are rejected.
- 7) ☒ Claim(s) 3-7,9,10,19-21,23,24 and 26-28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09601655.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

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### Detail d Action

The 101 rejection of claim 11, the 112, 2<sup>nd</sup> rejection of claims 16-17, the 102 (b) and 103 (a) rejections of claims 1, 11, 13, 14, 15, and 16, 17, and 18 are withdrawn in light of applicant's amendment at paper no. 12.

(new rejections)

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the method of preventing fungal diseases or fungi. It is also not established in the art to prevent fungal diseases or fungi. Most drugs do not prevent but treat disease. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The claims as recited are broader than the scope of enablement.

The applicant is referred to *In re Wands*, 858 f.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) which includes the incorporation of the 8 factors recited in Ex parte foreman 230 USPQ 546 (Bd. Of App. And Inter 1986).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy

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the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art 6) the amount of direction provided by the inventor 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In *re Wands*, 858 F. 2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

In terms of the breadth of the claims, R2 encompasses a much wider Markush grouping of radicals than those tested in the specification. 2) the nature of the invention which is that these compounds are used to treat diseases associated with fungi and are antifungal agents 5) level of predictability in the art. The compounds tested show a wide ranging difference in antifungal activity for similar structures. For example, compounds 53 and 56 only differ at the R2 radicals in Table 2 where for compound 53, R2 is NO<sub>2</sub> and for compound 56, R2 is (CH<sub>3</sub>)<sub>2</sub>N. Yet the antifungal activity for compound 53 for an 0.025 amount of sample used is 12, whereas the antifungal activity for compound 56 for an 0.025 amount of sample used is 0. The level of predictability regarding antifungal activity is low. The level of predictability regarding antifungal applicant is not tested against the whole breadth of Markush groups that R2 can equal which are any aromatic carboxylic residue other than those excluded in claim 1, page 2 of the amendment at paper no. 12. 7) the existence of working examples. The applicant doesn't test the whole breadth of compounds encompassing the whole breadth of the moieties that R2 can be in formula I in claim 1 of page 2 of the

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amendment at paper no. 12. In terms of the 8<sup>th</sup> Wands factors, undue experimentation would be required to make or use the invention based on the content of the disclosure due to the breadth of the claims, the level of predictability in the art of the invention, and the poor amount of direction provided by the inventor. Taking the above factors into consideration, it is not seen where the instant claim is enabled by the instant application.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim(s) 1 -2 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

*R2*  
A. In claim 1, line 7, the phrase "a protective group of amino" is indefinite. It is unclear as to which protective group the applicant is referring to.

*help?*  
B. In claim 2, lines 4-5 and all other occurrences in claim 22, the phrase "having a substituent" is indefinite. It is unclear as to which substituent the applicant is talking about.

C. In claim 25, line 6, page 5 of amendment 12, the phrase "at least one" is indefinite. There is no upper bound to this phrase. How many substituents is the applicant referring to?

3. If the applicant overcomes these rejections and is willing to restrict out the moieties of R2 in formula I of claim 1, page 2 of amendment at paper 12, equal to quinolinecarboxylic acid residue having a substituent, a pyrimidine carboxylic acid residue having a substituent, and a quinoxalinecarboxylic acid residue having a substituent, the case should be in condition for allowance.

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4. Claims 3-7, 9-10, 12-15, 19-24, and 26-28 are objected to because they are based on a rejected claim.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (703) 306-5437. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703)308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-7922 for regular communications and (703)308-7922 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0193.

Binta Robinson



November 18, 2001



**ALAN L. ROTMAN**  
**PRIMARY EXAMINER**